REMARKS

This paper is filed in response to the Office Action mailed September 2, 2010. Claims 1-9, 20-26, 34-38, 75-77, 79-81, and 83-89 were before the Examiner for consideration. In this paper, Claim 84 has been amended, no claims have been canceled, and new Claims 90 and 91 have been added. Accordingly, Claims 1-9, 20-26, 34-38, 75-77, 79-81, and 83-91 are now before the Examiner for consideration. No new matter has been added in these amendments.

Summary of the Office Action

In the Office Action, Claims 84 and 88 were rejected under 35 U.S.C. § 102(b) as being anticipated by Lafontaine (U.S. Patent No.6,520,939). Claims 85-87 and 89 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine in view of Haberland et al. (U.S. Patent Application Publication No.2005/0165433). Claims 1, 3-9, 20-24, 34, 75, and 76 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine in view of Haberland. Claim 2 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine and Haberland further in view of Fischell et al. (U.S. Patent No. 6,017,328). Claims 25-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine in view of Haberland further in view of Green et al. (U.S. Patent No.6,497,716). Claims 35-38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine in view of Haberland further in view of Willis et al. (U.S. Patent No. 6,767,340). Claims and 77, 79, 80, and 81 were

rejected under 35 U.S.C. §103(a) as being unpatentable over Lafontaine in view of Willis. Claim 83 was rejected under 35 U.S.C. §103(a) as being unpatentable over Lafontaine in view of Willis and further in view of Haberland. For at least the reasons discussed below, Applicant respectfully traverses these rejections.

The Office Action Improperly Construes Certain Claim Terms as 'Product-by-Process' Limitations.

Each of the pending independent claims recites certain terms construed in the Office Action to be "product-by-process" limitations and effectively accorded no patentable weight in the Office Action in evaluating the device recited therein. More specifically, independent Claims 1, 77, and 84 each recite, among other limitations, "a septum seal integrally formed," with a tubular member. Dependent Claim 88 recites that a septum seal and a zero seal are "formed in a monolithic construction."

But, the terms "integrally formed" and "formed in a monolithic construction" relate to structural features of the recited elements that, for reasons previously discussed in prosecution of the present Application are not disclosed in the applied art. For example, "integrally formed" and "formed in a monolithic construction" connote that various elements of a device have been formed as *a single piece*. The Court of Appeals for the Federal Circuit has repeatedly held that "words of limitation that can connote with equal force a structural characteristic of the product or a process of manufacture are commonly and by default interpreted in their structural sense, unless

the patentee has demonstrated otherwise." (3M Innovative Prods. Co. v. Avery Denison Corp., 350 F.3d 1365, 1371-72 (Fed. Cir. 2003) (*citing* Hazani v. United States Int'l Trade Comm'n, 126 F.3d 1473, 1479 (Fed. Cir. 1997) (concluding that "chemically engraved" was not a process term))). Furthermore, the Court of Appeals for the Federal Circuit has held that the term "integral" describes a structural relationship, rather that a process. (*See* Vanguard Prods. Co. v. Parker Hannifin Corp., 234 F.3d 1370, 1372 (Fed. Cir. 2000) ("We agree with the district court that the word 'integral' describes the relationship between the elastomeric layers, not the means of joining them.")). Moreover, the M.P.E.P. likewise recognizes the reasoning in this line of Federal Circuit cases and instructs Examiners that the "structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art . . . ." and that certain caselaw has held that "interbonded by interfusion" can limit the structure of the claimed composite and terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations. (M.P.E.P. § 2113, emphasis added).

Accordingly, for at least the reasons discussed above, the recitations indicated in the Office Action to be product-by-process terms should be accorded patentable weight as structural recitations. Thus, the claim rejections should be withdrawn and the pending claims reconsidered in view of the above discussion. With a proper reading of these recitations, the pending claims are distinguishable over the applied art for at least the reasons previously discussed and re-presented below.

The Office Action Has Been Improperly Made Final.

In the Office Action, it is indicated that "Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action." However, the only amendments to claims made in the most recent Amendment to the present Application, dated June 21, 2010, were responsive to rejections under 35 U.S.C. § 112. These § 112 rejections were not maintained in the present Office Action. Notably, no amendments were made to any of the independent claims in the most recent Amendment. Moreover, no new art has been substantively applied in the present Office Action.

Rather, in the present Office Action, the "new ground(s) of rejection" appear to be primarily directed to the construction of certain claim terms as "product-by-process" limitations. However, the term "integrally formed" was first presented in Claim 1 in the application as-filed (in 2004), and, over the course of several subsequent Office Actions (each relying on the same primary reference), this term has never previously been indicated to be a "product-by-process" limitation. Accordingly, the Final Action in this instance does not comport with the Final Office Action practice as set forth in the M.P.E.P.. Instead, the present application falls within the stated exception, where a Final Office Action is not indicated. (See, M.P.E.P. § 706.07(a), stating "Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by

applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)) (emphasis added).

In this instance, Applicant is filing a Request for Continued Examination in order to expedite prosecution of the pending claims.

New Claims 90 and 91.

Claims 90 and 91 have been added herein to further define the subject matter of the present Application. Claims 90-91 depend from Claim 84 and recite additional novel and nonobvious recitations thereon. Accordingly, these claims are distinguishable over the applied art for at least the reasons discussed herein with respect to Claim 84.

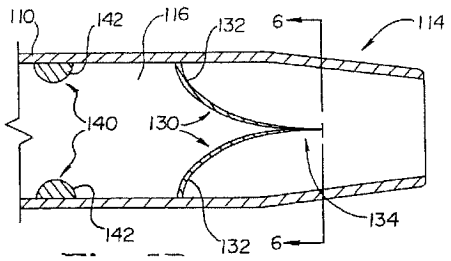
The Recited Subject Matter Is Distinguishable over Lafontaine.

As noted above, in the Office Action, Claims 84 and 88 were rejected as being anticipated by Lafontaine. For at least the reasons discussed below, Applicant respectfully traverses these rejections.

Lafontaine relates to a hemostasis valve for use with vascular introducer sheaths, catheters, Y-adapters, and the like. (Lafontaine, col. 1, lines 6-9). As illustrated in Figure 5A, reproduced below, Lafontaine describes an introducer sheath

including an active hemostasis valve 130 and a passive hemostasis valve 140. (Lafontaine, col. 4, lines 6-7). The active hemostasis valve 130 comprises a plurality of leaflets or flaps 132. (Lafontaine, col. 4, lines 30-31). The passive hemostasis valve 140 is normally open to allow devices to freely pass therethrough, and comprises a flexible polymeric O-ring sized to create either an interference fit or a gap fit with a device inserted therethrough. (Lafontaine, col. 4, lines 47-64).

Fig. 5A



Lafontaine teaches away from using a "gasket" seal comprising a disk with the device disclosed therein. In connection with the background to the Lafontaine device, Lafontaine does describe a "gasket" comprising a "disc of flexible polymeric material having" a hole or slit therethrough. (See, e.g., Lafontaine, col. 1, lines 27- 41, Figures 2A, 2B). However, Lafontaine describes these gasket configurations only in relation to admitted prior art vascular access systems that, unlike the access device recited in Claim 1, do not include another seal. Furthermore, Lafontaine emphasizes perceived undesirable performance characteristics of each of these gasket configurations to assert the desirability of the O-ring. (Lafontaine, col. 1, lines 42-55). Thus, Lafontaine teaches away from using one of the described gaskets as either an active hemostasis

valve or a passive hemostasis valve in the described surgical access device.

In contrast to the Lafontaine device, Claim 84 relates to a surgical access device comprising, among other limitations, an elongate tubular and a seal system at the distal end of the tubular member. The seal system comprises, among other limitations, "a septum seal comprising a septum having an orifice sized and configured to seal in conjunction with a specific range of usable instruments" and "a zero seal coupled to the septum seal and being sized and configured to seal when no instrument is in place within the working channel of the tubular member." Claim 88 depends from Claim 84 and further recites that "the septum seal and the zero seal are formed in a monolithic construction."

As discussed above, Lafontaine fails to disclose a septum seal comprising a septum and an orifice as recited in Claim 84. Rather, Lafontaine describes an O-ring positioned in an elongate shaft to provide sealing under certain conditions. Applicant notes that during examination, the claim terms are entitled to their broadest reasonable interpretation, consistent with the interpretation that one of skill in the art would reach. (See, e.g., M.P.E.P. 2111). Applicant respectfully submits that there is no *reasonable* interpretation of a septum seal comprising a septum that would include the O-ring of the Lafontaine device.

Lafontaine likewise fails to disclose a septum seal and zero seal "formed in a monolithic construction," as recited in Claim 88. As previously discussed Lafontaine illustrates the O-ring with hatching to indicate it is a "juxtaposed different element" with

respect to the sheath, even though the valve of Figure 5A is expressly indicated to be an "integral part" of the sheath. (Lafontaine, col. 4, lines 18-22; 37 C.F.R. § 1.84(h)(3)). Thus, Lafontaine has disclosed an O-ring that has been separately formed and later integrated with the sheath, but not the recited "integrally formed" device. Accordingly, Applicant respectfully submits that there is no *reasonable* interpretation of "formed in a monolithic construction," that would include components separately formed and later assembled, as is asserted in the Office Action.

Accordingly, for at least the reasons discussed above, Lafontaine fails to disclose all of the recitations of Claims 84 and 88. Thus, Claims 84 and 88 are distinguishable over the applied art.

The Recited Subject Matter Is Distinguishable over Combinations the Lafontaine with Other References.

As noted above, Claims 85-87 and 89 were rejected as being unpatentable over Lafontaine interview of Haberland. Claims 85-87 and 89 depend from Claim 84 and recite additional novel and non-obvious limitations thereon. As discussed above, Lafontaine fails to disclose all of the recitations Claim 84. Haberland likewise fails to disclose the deficiencies of the Lafontaine with respect to Claim 84. For example, as noted above, Lafontaine fails to disclose a surgical access device comprising a seal system at the distal end of an elongate tubular member having "a septum seal

comprising a septum." Haberland likewise fails to disclose a seal system at the distal end of an elongate tubular member having a septum seal. Rather, Haberland relates to a trocar system including a valve housing detachably connected to a proximal portion of a cannula body and at least one septum valve positioned in the valve housing. Haberland, paragraph [0013]). Accordingly, while Haberland does describe a construction process for a proximally-positioned cap assembly 30 in paragraphs [0048] and [0049], Haberland fails to disclose or suggest such a process for a seal system "at the distal end" of a tubular member, as recited in Claim 84.

Accordingly, for at least the above reasons, Claim 84 is distinguishable over the combination of Lafontaine and Haberland. Thus, Claims 85-87 and 89, which depend from Claim 84 are likewise distinguishable over the applied combination of references.

As noted above, Claims 1, 3-9, 20-24, 34, 75, and 76 were rejected as being unpatentable over the combination of Lafontaine with Haberland. For at least the reasons discussed below, Applicant respectfully traverses these rejections.

Claim 1 relates to a surgical access device comprising, among other recitations, an elongate tubular member, a septum seal integrally formed at the distal end of the tubular member, and a zero seal disposed at the distal end of the tubular member and distal to the septum seal. The septum seal comprises, among other limitations, “an elastomeric sheet having a frusto-conical shape and an orifice through the elastomeric

sheet."

As discussed above, Lafontaine fails to disclose or suggest a septum seal as recited in Claim 1, given its broadest reasonable interpretation consistent with the interpretation one skilled in the art would reach. Rather, Lafontaine describes an O-ring positioned in an elongate shaft to provide sealing under certain conditions. While Lafontaine does indicate that the O-ring can be "an integral part" of the device as opposed to a releasably connected assembly, Lafontaine fails to disclose or suggest that the O-ring is integrally formed with the tubular structure. (Lafontaine, col. 4, lines 13-22). Instead, Lafontaine illustrates the O-ring with hatching to indicate it is a "juxtaposed different element" with respect to the sheath, even though the valve of Figure 5A is expressly indicated to be an "integral part" of the sheath. (Lafontaine, col. 4, lines 18-22; 37 C.F.R. § 1.84(h)(3)). Thus, Lafontaine has disclosed an O-ring that has been separately formed and later integrated with the sheath, but not the recited "integrally formed" device.

Haberland fails to remedy to the deficiencies of Lafontaine with respect to Claim 1. For example, Haberland fails to disclose a septum seal that has a frusto-conical shape or that is "integrally formed" at the distal end of a tubular member. Haberland relates to a device having a "planar" septum seal having a "relatively flat thin profile". (Haberland, title, paragraph [0055]). Haberland illustrates a septum valve having a planar valve body 55 with a valve opening 51 "adapted to individually and separately receive a plurality of different elongate tools," to maintain a septum seal between

peripheries of the valve body 55 surrounding the valve opening 51 and abuttingly contacting outer peripheries of one of the tools extending therethrough. (Haberland, paragraph [0043], Figure 15c). The septum valve includes a periphery valve section 57 with convolutes 58 and rib portions 59 about the periphery thereof. (Haberland, paragraph [0044]). The periphery valve section 57 does not form a septum seal with tools inserted therethrough. Accordingly, Haberland fails to disclose a septum seal having a frusto-conical shape, as recited in Claim 1.

Furthermore, Haberland fails to disclose or suggest a septum seal that is "integrally formed" at the distal end of the tubular member, as recited in Claim 1. Rather, as discussed above, in the Haberland device, a septum valve is positioned within a valve housing at the proximal end of a cannula. Thus, the Haberland valve members are not "integrally formed," nor positioned at the distal end of the tubular member, as recited in Claim 1.

-- One Skilled in the Art Would Be Dissuaded by Lafontaine from Incorporating a Valve Member from the Haberland Device Therein.

As discussed above, Lafontaine fails to disclose all of the elements of the recited surgical access device. For example, Lafontaine fails to disclose a septum seal comprising an elastomeric sheet having a frusto-conical shape and an orifice through the elastomeric sheet, as is recited in Claim 1. Furthermore, one skilled in the art would be dissuaded by Lafontaine from modifying the device therein to include a valve

member as described in Haberland. Rather, as discussed above, Lafontaine teaches away from the use of a disk-shaped "gasket" similar to the valve members of Haberland, repeatedly emphasizing the perceived disadvantages of these valve members.

Accordingly, for at least the reasons discussed above, Claim 1 is distinguishable over the applied art. Claims 3-9, 20-24, 34, and 75-76 depend from Claim 1 and recite additional novel and nonobvious limitations thereon. Therefore, Claims 3-9, 20-24, 34, and 75-76 are distinguishable over the applied art for at least the reasons discussed above with respect Claim 1.

The Recited Subject Matter Is Distinguishable over the Applied Combination of Lafontaine, Haberland, and Fischell.

As noted above, Claim 2 was rejected as being unpatentable over Lafontaine and Haberland further in view of Fischell. For at least the reasons discussed below, Applicant respectfully traverses this rejection.

Claim 2 depends from Claim 1 and recites additional novel and nonobvious limitations thereon. For at least the reasons discussed above, Claim 1 is distinguishable over the applied combination of Lafontaine and Haberland. Fischell likewise fails to disclose or suggest the deficiencies of Lafontaine and Haberland with respect to Claim 1. For example, Fischell fails to disclose or suggest a device having a septum seal having a frusto-conical shape that is "integrally formed" at the distal end of

a tubular member. Rather, Fischell relates to injection ports for sub-cutaneous delivery of medication that includes a one-piece main body 11 and a separate self-sealing, soft, disk-shaped elastomer septum 22 positioned within the main body 11. (Fischell, col. 1, lines 10-11, col. 5, lines 36-39, col. 6, lines 4-8).

Accordingly, for that least the reasons above, the applied combination of references fails to disclose or suggest all of the recitations of Claim 1, from which Claim 2 depends. Thus, Claim 2 is distinguishable over the applied combination of references.

The Recited Subject Matter Is Distinguishable over the Applied Combination of Lafontaine, Haberland, and Green.

As noted above, Claims 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine and Haberland in view of Green et al. Claims 25 and 26 depend from Claim 1 and recite additional novel and nonobvious limitations thereon. As discussed above, the applied combination of Lafontaine and Haberland fails to disclose or suggest all of the limitations of Claim 1. Green appears to have been relied on in the Office Action solely for its asserted disclosure of a specific shape of certain portions of a placement device. Green thus fails to disclose or suggest the deficiencies of Lafontaine and Haberland with respect to Claim 1.

Accordingly, for at least the reasons discussed above, the applied combination of references fails to disclose or suggest all of the limitations of Claim 1, from which

Claims 25 and 26 depend. Therefore, at least for the reasons that Claim 1 is distinguishable over the applied combination of references, Claims 25 and 26 are distinguishable over the applied combination of references.

The Recited Subject Matter Is Distinguishable over the Applied Combination of Lafontaine, Haberland, and Willis.

As noted above, Claims 35-38 were rejected as being unpatentable over Lafontaine in view of Haberland further in view of Willis. Claims 35-38 depend from Claim 1 and recite additional novel and nonobvious limitations thereon. As discussed above, the applied combination of Lafontaine and Haberland fails to disclose or suggest all of the limitations of Claim 1. Willis appears to have been relied on in the Office Action solely for its asserted disclosure of certain aspects of a duckbill seal. Willis thus fails to disclose or suggest the deficiencies of Lafontaine and Haberland with respect to Claim 1.

Accordingly, for at least the reasons discussed above, the applied combination of references fails to disclose or suggest all of the limitations of Claim 1, from which Claims 35-38 depend. Therefore, at least for the reasons that Claim 1 is distinguishable over the applied combination of references, Claims 35-38 are distinguishable over the applied combination of references.

The Recited Subject Matter Is Distinguishable over the Applied

Combination of Lafontaine and Willis.

As noted above, Claims 77, 79, 80, 81 were rejected as being unpatentable over Lafontaine in view of Willis. Claimed 77 relates to a surgical access device, comprising, among other limitations, an elongate tubular member, a septum seal integrally formed at the distal end of the tubular member, the septum seal comprising an elastomeric sheet and an orifice through the elastomeric sheet, and a duckbill valve positioned distal of the septum seal. For at least the reasons discussed above with respect to Claims 1 and 84, Lafontaine fails to disclose suggest the recited septum seal. Willis likewise fails to disclose or suggest a septum seal as recited. Willis describes that a duckbill valve is formed from flange portion 68 and walls 70 and 72. (Willis, col. 3, line 60-col. 4, line 1). Moreover, in Figure 4, asserted in the Office Action to show an orifice through a septum, Willis illustrates an external side view of a valve member. Figure 3, which illustrates a cross-sectional view of the Willis device, plainly shows no septum seal, as recited in Claim 77.

Accordingly, for at least the reasons discussed above, the applied combination of references fails to disclose or suggest all of the limitations of Claim 77. Claims 79, 80, and 81 depend from Claim 77 and recite additional novel and non-obvious limitations thereon. Therefore, at least for the reasons that Claim 77 is distinguishable over the applied combination of references, Claims 79, 80, 81 are distinguishable over the applied combination of references.

The Recited Subject Matter Is Distinguishable over the Applied Combination of Lafontaine, Willis, and Haberland.

As noted above, Claim 83 was rejected as being unpatentable over Lafontaine in view of Willis further in view of Haberland. Claim 83 depends from Claim 77 and recites novel and nonobvious limitations thereon. For at least the reasons discussed above, Claim 77 is distinguishable over the combination of Lafontaine and Willis. Haberland fails to remedy the deficiencies of Lafontaine and Willis with respect to Claim 77. For example, as discussed in greater detail above, none of Lafontaine, Willis, and Haberland, alone or in combination, disclose or suggest "a septum seal integrally formed at the distal end of the tubular member, the septum seal comprising an elastomeric sheet and an orifice through the elastomeric sheet."

Accordingly, for at least the reasons discussed above, Claim 77 is distinguishable over the combination of Lafontaine, Willis, and Haberland. Thus, Claim 83, which depends from Claim 77 is distinguishable over the applied combination of references for at least the reasons discussed above with respect to Claim 77.

Conclusion

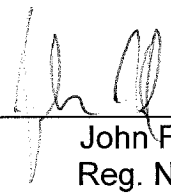
For at least the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowability is most earnestly solicited.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, John F. Heal, at (949) 713-8283 to resolve such issues promptly.

Respectfully Submitted,

APPLIED MEDICAL RESOURCES

BY 

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